

APPENDIX II-C

RULEMAKING NOTICE FORM

Notice Number	2021-83	Rule Number	He-P 2101.01, He-P 2102.02, He-P 2102.05, and He-P 2107.01
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<p>1. Agency Name & Address:</p> <p>Dept. of Health & Human Services Division of Public Health Service Food Protection Services 29 Hazen Drive Concord, NH 03301</p>	<p>2. RSA Authority: RSA 143:6, I and II(a)-(c) and RSA 143-A:9, I and II</p> <p>3. Federal Authority: _____</p> <p>4. Type of Action:</p> <p>Adoption _____</p> <p>Repeal _____</p> <p>Readoption _____</p> <p>Readoption w/amendment X</p>
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5. Short Title: **Beverages and Bottled Water**

6. (a) Summary of what the rule says and of any proposed amendments:

He-P 2100 specifies requirements for the registration and licensing for in-state and out-of-state beverage and bottled water manufacturers including procedures for applications and inspections. He-P 2100 also specifies fees that are charged for annual applications, and inspections and enforcement provisions for non-compliance with the rule.

The Department of Health and Human Services (Department) is proposing to readopt with amendment various provisions of He-P 2100, specifically:

- **He-P 2101.01 containing all definitions for He-P 2100, by adding the definition of “maximum containment level (MCL)”;**
- **He-P 2102.02 on standards of quality for bottled water, by adding the requirement that finished product bottled water shall meet the maximum containment level requirements as specified in Env-Dw 702 through Env-Dw 705 where there are no standards for those compounds included in 21 CFR 165.110. This would apply to Methyl Tertiary-Butyl Ether (MtBE) and Per- and Polyfluoroalkyl Substances (PFAS) contaminants;**
- **He-P 2102.05 on bottled water sample requirements, so that all samples of bottled water sources or finished product, located within the continental United States, shall be analyzed in a laboratory that has been accredited according to Env-C 300 and that all samples of bottled water sources or finished product, located outside of the continental United States, shall be analyzed in a laboratory that has been accredited according to Env-C 300 or ISO 17025; and**
- **He-P 2107.01 on submission of initial registration applications, to require applicants to certify that the water quality requirements are met and that testing results for Methyl Tertiary-Butyl Ether (MtBE) Per- and Polyfluoroalkyl Substances (PFAS) contaminants have been submitted with new and renewal applications.**

6. (b) Brief description of the groups affected:

These rules affect the manufacturers and bottlers of beverages and bottled water.

6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

Rule	Specific State or Federal Statute or Federal Regulation the Rule Implements
He-P 2101.01	RSA 143:9; RSA 143:16; 9 CFR 318.30 & 21 CFR 165.110
He-P 2102.02	RSA 143:16; RSA 485:3; 21 CFR 165.110
He-P 2102.05	RSA 143:16
He-P 2102.05	RSA 143:16
He-P 2107.01	RSA 143:12

7. Contact person for copies and questions including requests to accommodate persons with disabilities:

Name: **Allyson Zinno** Title: **Administrator- Administrative Rules Unit**
Address: **Dept. of Health and Human Services** Phone #: **(603) 271-9604**
Administrative Rules Unit Fax#: **(603) 271-5590**
129 Pleasant Street, 2nd Floor E-mail: Allyson.E.Zinno@dhhs.nh.gov
Concord, NH 03301

TTY/TDD Access: Relay NH 1-800-735-2964
or dial 711 (in NH)

The proposed rules may be viewed and downloaded at:

<http://www.dhhs.nh.gov/oos/aru/comment.htm>

8. Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified: **Friday, September 17, 2021**

☒ Fax

☒ E-mail

☐ Other format (specify):

9. Public hearing scheduled for:

Date and Time: **Friday, September 10, 2021 at 11:00 am**

Place: [**DHHS Brown Bldg., Auditorium, 129 Pleasant St., Concord, NH**](#)

10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant)

FIS # 21:072 , dated July 27, 2021

1. Comparison of the costs of the proposed rule(s) to the existing rule(s):

When compared to the existing rule, the proposed rule may increase costs to independently-owned businesses.

2. Cite the Federal mandate. Identify the impact on state funds:

No federal mandate, no impact on state funds.

3. Cost and benefits of the proposed rule(s):

A. To State general or State special funds:

None.

B. To State citizens and political subdivisions:

None.

C. To independently owned businesses:

The Department of Health and Human Services states the proposed rule will result in a potential cost to bottled water manufacturers that are not currently testing their products for Methyl tertiary-butyl ether (MtBE) or Per- and Polyfluoroalkyl Substances (PFAS) contaminants. This analysis is estimated to cost \$175-\$400 per sample.

11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

The proposed rules modify an existing program or responsibility, but do not mandate any fees, duties, or expenditures on the political subdivisions of the state, and therefore do not violate Part I, Article 28-a of the N.H. Constitution.

CHAPTER He-P 2100 BEVERAGES AND BOTTLED WATER

PART He-P 2101 DEFINITIONS

Readopt with amendment He-P 2101.01, effective 11-27-18 (Document #12680), to read as follows:

He-P 2101.01 Definitions.

- (a) “Adequate” means that which is needed to accomplish the intended purpose.
- (b) “Approved source” means the source(s) of the water and the water therefrom, which has been approved by the New Hampshire department of environmental services (DES) in accordance with RSA 143:16 or RSA 485:3.
- (c) “Artesian water” means “artesian water” as defined in 21 CFR 165.110 (a)(2)(i), namely “water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer.”
- (d) “Beverages” means “beverage” as defined in RSA 143:9, namely “all still and carbonated drinks, fruit juices and all beverages compounded therefrom; all bottled waters, whether for medicinal or table use; and all packaged liquids intended for use in the manner of drink. Milk and unmixed products thereof, and fruit juices and waters retailed exclusively by the producer or manufacturer direct, are not included.”
- (e) “Bottled water” means “bottled water” as defined in 21 CFR 165.110(a)(1).
- (f) “Bottler” means any person, firm, or corporation engaging in the business of bottling beverages and/or water for sale or distribution.
- (g) “Bulk water” means a source of water, not bottled by its owner, but which is transported via tanker truck or an equivalent means from one area to another for the purpose of treatment, packaging and human consumption.
- (h) “Commissioner” means the commissioner of the New Hampshire department of health and human services or his or her designee.
- (i) “Compliant facility” means a facility that achieves a score of 90 or greater on an inspection, in accordance with He-P 2108.01.
- (j) “Corrosion resistant material” means those materials that maintain their original surface characteristics when exposed to the conditions encountered during intended use including expected contact with product and cleaning, sanitizing or sterilization compounds or solutions.
- (k) “Deionized water” means “deionized water” as defined in 21 CFR 165.110(a)(2)(iv), namely water that “has been processed by deionization.”
- (l) “Demineralized water” means “demineralized water” as defined in 21 CFR 165.110(a)(2)(iv), namely “water that has been produced by distillation, deionization or reverse osmosis, or other suitable processes and that meets the definition of ‘purified water’ in the United States Pharmacopeia, 23rd Revision, January 1, 1995.”
- (m) “Department” means the New Hampshire department of health and human services.

(n) “Distilled water” means “distilled water” as defined in 21 CFR 165.110(a)(2)(iv), namely water that “has been produced by distillation.”

(o) “Imminent health hazard” means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance or event creates a situation that requires immediate correction or cessation of operation to prevent injury, based on the number of potential injuries and the nature, severity and duration of the anticipated injury.

(p) “Maximum contaminant level (MCL)” means “maximum contaminant level” as defined in RSA 485:1-a, VII.

~~(qp)~~ “Mineral water” means “mineral water” as defined in 21 CFR 165.110(a)(2)(iii), namely “water containing not less than 250 parts per million (ppm) total dissolved solids (TDS) coming from a source tapped at one or more bore holes or springs, originating from a geologically and physically protected underground water source.”

~~(rq)~~ “Multiservice containers” means containers intended for use more than one time.

~~(sf)~~ “Natural water” means ground water that is not modified in its mineral content by addition or subtraction except the modification that might occur through minimal treatment such as filtration, aeration, ozonation, ultraviolet light or equivalent disinfection processes intended to remove undesirable elements.

~~(ts)~~ “Non-compliant facility” means a facility that scores less than 90 on an inspection, in accordance with He-P 2108.01.

~~(ut)~~ “Nontoxic materials” means materials for product contact surfaces utilized in the transporting, processing, storing and packaging of bottled beverages or drinking water, which are free of substances which could render the water injurious to health or which could adversely affect the flavor, color, odor or bacteriological quality of the beverage or water.

~~(v#)~~ “Operations water” means water which is delivered under pressure to a plant for container washing, hand washing, plant and equipment cleanup and for other sanitary purposes.

~~(wv)~~ “Person” means an individual or firm, partnership, company, corporation, trustee, association or any public or private entity.

~~(xw)~~ “Primary container” means the immediate container in which product water is packaged.

~~(y*)~~ “Processing authority” means “processing authority” as defined in 9 CFR 318.300 (q), namely “the person(s) or organization(s) having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions as indicated in this subpart.”

~~(zy)~~ “Product water” means water that is processed by a plant for bottled drinking water or for the manufacture of beverages.

~~(aa#)~~ “Purified water” means “purified water” as defined in 21 CFR 165.110 (a)(2)(iv), namely “water that has been produced by distillation, deionization, reverse osmosis, or other suitable processes, and which meets the definition of ‘purified water’ in the United States Pharmacopeia, 23rd Revision, January 1, 1995.”

(~~abaa~~) “Sanitize” means the application of cumulative heat, chemicals or equivalent processes on cleaned product contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to 99.999% reduction of representative disease microorganisms of public health importance.

(~~acab~~) “Single-service container” means a container intended for one time usage only.

(~~adae~~) “Sparkling bottled water” means “sparkling bottled water” as defined in 21 CFR 165.110 (a)(2)(v), namely “water that after treatment and possible replacement with carbon dioxide, contains the same amount of carbon dioxide from the source that it had at emergence from the source.”

(~~aead~~) “Spring water” means “spring water” as defined in 21 CFR 165.110 (a)(2)(vi), namely “water derived from an underground formation from which water flows naturally to the surface of the earth.”

(~~afae~~) “Sterile water” means “sterile water” as defined in 21 CFR 165.110 (a)(2)(vii), namely “water that meets the requirements under ‘Sterility Tests’ in the United States Pharmacopeia, 23rd Revision, January 1, 1995.”

(~~agaf~~) “Unit package” means a standard commercial package of a beverage or bottled drinking water.

(~~ahag~~) “Vended water” means water that is dispensed by a water vending machine that is not placed by a bottler in sealed containers.

(~~aiah~~) “Wash” means cleaning with a solution that contains soap, detergent, acid cleaner, alkaline cleaner, or other cleaning agents according to the cleaning agents manufacturing label instructions.

(~~ajai~~) “Well water” means “well water” as defined in 21 CFR 165.110 (a)(2)(viii), namely “water from a hole bored, drilled, or otherwise constructed in the ground which taps the water of an aquifer.”

PART He-P 2102 BOTTLED, BULK AND VENDED WATER

Readopt with amendment He-P 2102.02, effective 11-27-18 (Document #12680), to read as follows:

He-P 2102.02 Standards of Quality for Bottled Water.

(a) All sources of water for bottled, bulk, or vended water, under the regulatory authority of DES shall meet the quality standards required by DES in accordance with RSA 485:3.

(b) All finished bottled water products, regardless of state or country of origin, shall meet the FDA standards of quality for bottled water in 21 CFR 165.110(b) and the maximum contaminant level (MCL) requirements of Env-Dw 702 through 705.

(c) For standards that are included in both 21 CFR 165.110 and in Env-Dw 702-705, the level set in 21 CFR 165.110 (b) shall be used.

Readopt with amendment He-P 2102.05, effective 11-27-18 (Document #12680), to read as follows:

He-P 2102.05 Bottled Water Sample Requirements.

(a) All samples of bottled water sources or finished product, located within the continental United States, shall be analyzed in a laboratory which has been ~~certified by the Environmental Protection Agency (EPA) or which has been certified or~~ accredited according to Env-C 300.

(b) All samples of bottled water sources or finished product, located outside the continental United States, shall be analyzed in a laboratory which has been accredited according to Env-C 300 or ISO 17025.

~~(c)~~ To assure that the plant's production of bottled water is in compliance with the quality standards set forth in He-P 2102.02, the plant ownership shall collect samples of finished product for analysis as follows:

(1) For microbiological standards, analyze, at least once each week, a sample from a batch or segment of the continuous production for each type of finished bottled water produced by the plant; and

(2) For chemical, physical, and radiological standards, analyze, at least once each calendar year, a sample from a batch or segment of a continuous product run for each type of finished bottled water produced by the plant.

(c) The samples required by (1) and (2) above shall be derived from primary containers or unit packages of the product.

PART He-P 2107 REGISTRATION OF OUT-OF-STATE BEVERAGES AND BOTTLED WATER

Readopt with amendment He-P 2107.01, effective 11-27-18 (Document #12680), to read as follows:

He-P 2107.01 Submission of Initial Registration Applications.

(a) All applicants registering their products in accordance with RSA 143:12 shall complete and submit to the department Form OSB APP "Application for Beverage and Bottled Water Registration" (October ~~2021~~²⁰¹⁸ Edition), obtained from the department or available at <https://www.dhhs.nh.gov/dphs/fp/beverage/license.htm>, affirming and certifying the following:

"I certify that all information provided in or attached to this application is complete, accurate and up-to-date as of the date specified below. I further certify that there are no willful misrepresentations of the answers to questions herein, and that I have made no omissions with respect to any of my answers to the questions presented. I certify that any bottled water that I am registering meets the standards of quality in He-P 2102.02(b). I understand that it is my responsibility to immediately notify the Food Protection Section with regard to any changes, corrections or updates to the information provided.

(b) The applicant shall include the following information in the application submittal:

(1) A copy of a sanitary inspection conducted within the previous 12 months by the regulatory authority with jurisdiction or a recognized national third party audit organization, a letter from the regulatory authority confirming compliance with local regulations or a health certificate for the bottling facility issued within the previous 12 months; and

(2) If the product is bottled water, a copy of the approval of the source for bottled water, including the approval for the designation "spring water", if the product is labeled as such,

issued by the federal, state, local, provincial or other government agency with the authority to approve sources for bottled water.

(3) If the product is bottled water, a copy of laboratory analysis for Methyl tertiary-butyl ether (MtBE) based on the specified Maximum Contaminant Level (MCL) in Env-Dw 705.01 and Per- and Polyfluoroalkyl Substances (PFAS) Contaminants based on the specified MCLs -in Env-Dw 705.06 in accordance with He-P 2102.05, of the finished product;

(4) The analyses required by (3) above shall be conducted not more than 6 months prior to the date of the application by an approved laboratory in accordance with He-P 2102.05(a).

(c) Cash, check, money order, or online payment for the application fee of \$400, in accordance with RSA 143:12 shall be submitted with the registration application.

(d) Upon receipt of an application for registration and appropriate registration fee, the commissioner shall approve or deny the application in accordance with He-P 2107.04.

Appendix

Rule	Specific State or Federal Statute or Federal Regulation the Rule Implements
He-P 2101.01	RSA 143:9; RSA 143:16; 9 CFR 318.30 & 21 CFR 165.110
He-P 2102.02	RSA 143:16; RSA 485:3; 21 CFR 165.110
He-P 2102.05	RSA 143:16
He-P 2102.05	RSA 143:16
He-P 2107.01	RSA 143:12